

## § 201.63

## 21 CFR Ch. I (4–1–02 Edition)

2 in),” “90 inches (2½ yd),” “30 inches (2.5 ft),” “¾ inch by 36 in (1 yd),” etc.

(n) On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable (1 square foot or more), the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, “158 sq inches (1 sq ft 14 sq in).”

(o) Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in nondeceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the drug contained in the package; for example, “giant pint” and “full quart.” Dual or combination declarations of net quantity of contents as provided for in paragraphs (a) and (i) of this section are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

(p) A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

(q) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

(r) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled “sample,” “physi-

cian’s sample,” or a substantially similar statement and the contents of the package do not exceed 8 grams.

### § 201.63 Pregnancy/breast-feeding warning.

(a) The labeling for all over-the-counter (OTC) drug products that are intended for systemic absorption, unless specifically exempted, shall contain a general warning under the heading “Warning” (or “Warnings” if it appears with additional warning statements) as follows: “If pregnant or breast-feeding, ask a health professional before use.” [first four words of this statement in bold type] In addition to the written warning, a symbol that conveys the intent of the warning may be used in labeling.

(b) Where a specific warning relating to use during pregnancy or while nursing has been established for a particular drug product in a new drug application (NDA) or for a product covered by an OTC drug final monograph in part 330 of this chapter, the specific warning shall be used in place of the warning in paragraph (a) of this section, unless otherwise stated in the NDA or in the final OTC drug monograph.

(c) The following OTC drugs are exempt from the provisions of paragraph (a) of this section:

(1) Drugs that are intended to benefit the fetus or nursing infant during the period of pregnancy or nursing.

(2) Drugs that are labeled exclusively for pediatric use.

(d) The Food and Drug Administration will grant an exemption from paragraph (a) of this section where appropriate upon petition under the provisions of § 10.30 of this chapter. Decisions with respect to requests for exemptions shall be maintained in a permanent file for public review by the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

(e) The labeling of orally or rectally administered OTC aspirin and aspirin-containing drug products must bear a warning that immediately follows the general warning identified in paragraph (a) of this section. The warning shall be as follows:

“It is especially important not to use” (select “aspirin” or “carbaspirin calcium,” as appropriate) “during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.”

[47 FR 54757, Dec. 3, 1982, as amended at 55 FR 27784, July 5, 1990; 59 FR 14364, Mar. 28, 1994; 64 FR 13286, Mar. 17, 1999]

#### § 201.64 Sodium labeling.

(a) The labeling of over-the-counter (OTC) drug products intended for oral ingestion shall contain the sodium content per dosage unit (e.g., tablet, teaspoonful) if the sodium content of a single recommended dose of the product (which may be one or more dosage units) is 5 milligrams or more. OTC drug products intended for oral ingestion include gum and lozenge dosage forms, but do not include dentifrices, mouthwashes, or mouth rinses.

(b) The sodium content shall be expressed in milligrams per dosage unit and shall include the total amount of sodium regardless of the source, i.e., from both active and inactive ingredients. The sodium content shall be rounded-off to the nearest whole number. The sodium content per dosage unit shall follow the heading “Other information” as stated in § 201.66(c)(7).

(c) The labeling of OTC drug products intended for oral ingestion shall contain the following warning under the heading “Warning” (or “Warnings” if it appears with additional warning statements) if the amount of sodium present in the labeled maximum daily dose of the product is more than 140 milligrams: “Do not use this product if you are on a sodium-restricted diet unless directed by a doctor.”

(d) The term *sodium free* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 0 milligram. For example, a product containing 0.4 (rounded-off to zero (0)) milligram sodium per tablet with directions to take one tablet daily may use the term “sodium free” in its labeling. However, when the recommended dose provides for taking more than one dosage unit per day, e.g., take one or two tablets, or take two tablets, the same product containing 0.4 milligram sodium per

tablet shall not use the term “sodium free” because the labeled maximum daily dose contains 0.8 milligram sodium.

(e) The term *very low sodium* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 35 milligrams or less.

(f) The term *low sodium* may be used in the labeling of OTC drug products intended for oral ingestion if the amount of sodium in the labeled maximum daily dose is 140 milligrams or less.

(g) The term *salt* is not synonymous with the term sodium and shall not be used interchangeably or substituted for the term *sodium*.

(h) The terms *sodium free*, *very low sodium*, and *low sodium* shall be in print size and style no larger than the product’s statement of identity and shall not be unduly prominent in print size or style compared to the statement of identity.

(i) Any product subject to this paragraph that contains sodium bicarbonate, sodium phosphate, or sodium biphosphate as an active ingredient for oral ingestion and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after April 22, 1997, is misbranded under sections 201(n) and 502 (a) and (f) of the Federal Food, Drug, and Cosmetic Act (the act).

[61 FR 17806, Apr. 22, 1996, as amended at 62 FR 19925, Apr. 24, 1997; 64 FR 13286, Mar. 17, 1999]

EFFECTIVE DATE NOTE: At 62 FR 19925, Apr. 24, 1997, the effective date for § 201.64 (a) through (h) was delayed until further notice.

#### § 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

(a) *Scope*. This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with